



GUIDANCE DOCUMENT FOR REPORTING THE IDENTIFICATION OF A SELECT BIOLOGICAL AGENT OR TOXIN IN A CLINICAL OR DIAGNOSTIC LABORATORY



INTRODUCTION

The "Public Health Security and Bioterrorism Preparedness Response Act of 2002" (Public Law 107-188) signed into law on June 12, 2002, requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It necessitates that individuals possessing, using or transferring agents or toxins deemed a threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select biological agents and toxins were published by HHS (42 CFR 73; December 13, 2002) and by USDA (9 CFR 121 and 7 CFR 331; December 13, 2002).

Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the Secretary, HHS, and to the Animal and Plant Health Inspection Service (APHIS) by the Secretary, USDA. In order to minimize the reporting burden to the public, HHS/CDC and the USDA/APHIS have developed a common reporting form for this data collection. This form is designed to assist facilities in complying with this legal obligation.

Clinical or diagnostic laboratories that have identified the following select biological agents and toxins from diagnostic or verification testing activities are required by law (42 CFR 73.6) to contact CDC immediately: Variola major virus (Smallpox virus) and Variola minor (Alastrim), *Bacillus anthracis*, *Yersinia pestis*, Botulinum neurotoxins, *Francisella tularensis*, Ebola viruses, Marburg virus, Lassa fever virus, and South American Hemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito). CDC should be contacted by telephone at 404-498-2255 or facsimile at 404-498-2265.

For USDA agents and toxins, the applicant should contact APHIS (for animal agents and toxins telephone: 301-734-3277; facsimile: 301-734-3652) For HHS/USDA overlap agents, the applicant should contact either APHIS or CDC at the numbers above. For plant agents and toxins the applicant should contact APHIS (telephone: 301-734-5519; facsimile: 301-734-8700). A listing of HHS select biological agents and toxins is available at <http://www.cdc.gov/od/sap>. A listing of USDA animal agents and toxins is available at <http://www.aphis.usda.gov/vs/ncie/bta.html>. The list of plant agents and toxins is available at <http://www.aphis.usda.gov/ppq/permits>.

The select biological agents and toxins obtained through diagnosis or verification must be destroyed or transferred to a registered entity within 7 days of identification. Select biological agents and toxins used for proficiency testing must be destroyed or transferred to a registered entity within 90 days after receipt. This form must be submitted to CDC or APHIS, as appropriate, within 7 days after identification of select biological agents or toxins.

INSTRUCTIONS

Entities or facilities that have obtained select biological agents and toxins through diagnosis or verification must complete sections 1, 2 or 3, and 5. Section 3 of the form allows for bi-weekly reporting by veterinary diagnostic entities or facilities that identify select biological agents or toxins in areas where the select biological agent is endemic or during outbreaks. An entity or facility may request bi-weekly reporting by submitting a request in writing to: National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231 or by faxing it to 301-734-3652.

Those entities or facilities that obtained select biological agents and toxins for proficiency testing must complete sections 1, 4, and 5. All forms must be signed and dated.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact the CDC at (404) 498-2255 or APHIS at (301) 734-3277. This guidance document and form are also available at <http://www.cdc.gov/od/sap>, <http://www.aphis.usda.gov/vs/ncie/bta.html> and <http://www.aphis.usda.gov/ppq/permits>.

WHERE TO SEND THE COMPLETED FORM

For HHS agents, return completed forms to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333.

For USDA animal agents and toxins, return completed forms to: National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231.

For HHS/USDA overlap select agents, return forms to: either CDC or APHIS at the addresses provided.

For USDA plant agents and toxins, return completed forms to: Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236



REPORT OF THE IDENTIFICATION OF A SELECT BIOLOGICAL AGENT OR TOXIN IN A CLINICAL OR DIAGNOSTIC LABORATORY



Read all instructions carefully before completing the form. Answer all items completely and type or print in ink. The form must be signed. For HHS agents, submit document to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333. For USDA animal agents, submit document to: National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231. For HHS/USDA overlap agents submit the form to either CDC or APHIS. For USDA plant agents and toxins, return completed forms to: Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236

SECTION 1 – TO BE COMPLETED BY LABORATORY DIRECTOR

Legal name of entity/facility		Entity registration number (if applicable) APHIS# _____ CDC# _____			
Address (NOT a post office address)			City	State	Zip Code
Name of laboratory director	Title	Telephone	FAX	E-mail	
Address (NOT a post office address)			City	State	Zip Code
Select agent being reported:		Name of laboratory supervisor:			
Name and strain designation of select biological agent (if known) / toxin:					
Provide any data regarding molecular, phenotypic, or morphological characterization of select agent(s):					
Location where work with specimens was conducted: Building: _____ Room: _____			Biosafety level of laboratory or PPQ containment designation:		

SECTION 2 – TO BE COMPLETED FOR SELECT BIOLOGICAL AGENTS AND TOXINS FROM CLINICAL/DIAGNOSTIC TESTING

INFORMATION ON AGENT/ TOXIN

- Source of select agent isolate(s):
- ☐ Clinical or diagnostic specimen (Specify from which species): _____
 ☐ Specimen type: ☐ Blood ☐ Tissue ☐ Other (specify): _____
- ☐ Environmental sample (specify type): _____
- ☐ Isolate (Specify laboratory that sent isolate): _____
- ☐ Other (specify): _____

INFORMATION ON CLINICAL CASE FROM WHICH THE SELECT BIOLOGICAL AGENT OR TOXIN WAS OBTAINED

Name of person most familiar with the case		Telephone
Description of the disease:		
Number of cases	Date first case observed	How diagnosis was made
Laboratory that confirmed original diagnosis		Name, address and phone of laboratory director

SECTION 3 – INFORMATION ON DIAGNOSTIC CASES FROM WHICH SELECT BIOLOGICAL AGENTS AND TOXINS WAS OBTAINED (OUTBREAK/ENDEMIC AREAS)		
Name of person most familiar with the case		Telephone
Description of the disease:		
Identification date of index case	Number of cases (bi-weekly total)	How diagnosis was made
Laboratory that confirmed original diagnosis	Name, address and phone of laboratory director	

SECTION 4 – TO BE COMPLETED FOR SELECT BIOLOGICAL AGENTS AND TOXINS FROM PROFICIENCY TESTING	
Entity/facility that you obtained select agent from: <input type="checkbox"/> College of American Pathologists <input type="checkbox"/> Registered entity (Name, CDC or APHIS registration number: _____) <input type="checkbox"/> Other (Explain): _____	Date obtained
Name of laboratory test that proficiency test was designed to assess:	

SECTION 5 – TO BE COMPLETED BY ALL ENTITIES / FACILITIES	
INFORMATION ON DESTRUCTION OR TRANSFER OF SELECT BIOLOGICAL AGENTS AND TOXINS	
Date(s) agent was isolated or toxin was detected	Amount of agent / toxin on site prior to destruction or transfer
Select agent was: <input type="checkbox"/> Transferred to a registered entity (give name, CDC or APHIS entity registration number, date, and CDC or APHIS confirmation number: _____) <input type="checkbox"/> Destroyed on site If destroyed on site: Date select agent was destroyed: _____ Method of destruction: _____ <input type="checkbox"/> Other (Provide detailed explanation) _____	
Is this source expected to provide additional specimens? <input type="checkbox"/> No <input type="checkbox"/> Yes	Anticipated quantity of specimens to be received:
Anticipated time period to receive specimen (give estimated end date):	

I certify that all select biological agents and toxins isolated by this entity/facility have been transferred or disposed of according to all Federal, State and local regulations. I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 42 CFR 73, 9 CFR 121, or 7 CFR 331 may result in civil or criminal penalties, including imprisonment.

Signature of Laboratory Director: _____ Typed or printed name: _____

Date: _____

Public reporting burden: Public reporting burden of providing this information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-24, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).